December 20, 2019

Nonin Medical, Inc.
Walter Holbein
Manager, RA/CA
13700 1st Avenue North
Plymouth, Minnesota 55441

Re: K191403
Trade/Device Name: Nonin Onyx 3, Model 9591
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: November 20, 2019
Received: November 25, 2019

Dear Walter Holbein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Todd Courtney
Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191403

Device Name
Nonin Onyx 3, Model 9591

Indications for Use *(Describe)*
The Nonin® Model 9591Onyx® 3 Finger Pulse Oximeter is a small, lightweight, portable and reusable spot-check device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate of patients who are well or poorly perfused. The Respiration Rate parameter provides a non-invasive measurement of respiration rate, in breaths per minute.

For %SpO2, and pulse rate, the 9591 is intended for use in hospitals, clinics, long-term care facilities, skilled nursing facilities, and home healthcare services. It is intended for adult and pediatric patients
who are well or poorly perfused, with digits that are between 0.3 – 1.0 inch (0.8 – 2.5 cm) thick, under non-motion conditions.

For Respiration rate, the 9591 is intended for use in hospitals, clinics, long-term care facilities, skilled nursing facilities, and home healthcare services. It is intended for adult who are well perfused, with digits that are between 0.3 – 1.0 inch (0.8 – 2.5 cm) thick, under non-motion conditions. It is not intended for use in high-acuity environments, such as ICU or operating rooms where continuous monitoring is expected.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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1. 510(k) Summary: K191403

Submitter: Nonin Medical, Inc.
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Plymouth, MN 55441-5443

Contact Person: Walter Holbein
RA/CA Manager

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Date Prepared: 20 May, 2019

Trade Name: Onyx® 3 Model 9591 Finger Pulse Oximeter

Common Name: Finger Pulse Oximeter

Classification Name: Oximeter

Regulation Number: Class II, 21 CFR 870.2700

Product Code, Panel: DQA, Anesthesiology

Predicate Device(s): Nonin Model 3230 Bluetooth® Smart Pulse oximeter cleared by the FDA under K131021 on 9/11/2013, and

Reference Device: Nellcor™ Bedside Respiratory Patient Monitoring System (PM1000N) cleared by the FDA under K141518 on 3/5/2015.

Device Description

The Model 9591 Finger Pulse Oximeter is a small, lightweight, portable, reusable, digit pulse oximeter that displays numerical values for functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate by measuring the absorption of red and infrared (IR) light passing through perfused tissue. The SpO_2, pulse rate, and respiration rate are displayed on the LCD display contained within the device. A color LCD provides a visual indication of the pulse signal, while blinking at the corresponding pulse rate. The display will indicate of poor pulse quality that may affect the readings. The Respiration Rate parameter provides a non-invasive measurement of respiration rate, in breaths per minute. It is intended for spot-checking of adult and pediatric patients who are well or poorly perfused with digits that are between 0.3 – 1.0 inch (0.8 – 2.5 cm) thick.

Intended Use:	**Model 9591** The Nonin® Model 9591Onyx® 3 Finger Pulse Oximeter is a small, lightweight, portable and reusable spot-check device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate of patients who are well or poorly perfused. The Respiration Rate parameter provides a non-invasive measurement of respiration rate, in breaths per minute. For %SpO2, and pulse rate, the 9591 is intended for use in hospitals, clinics, long-term care facilities, skilled nursing facilities, and home healthcare services. It is intended for adult and pediatric patients who are well or poorly perfused, with digits that are between 0.3 – 1.0 inch (0.8 – 2.5 cm) thick, under non-motion conditions. For Respiration rate, the 9591 is intended for use in hospitals, clinics, long-term care facilities, skilled nursing facilities, and home healthcare services. It is intended for adult who are well perfused, with digits that are between 0.3 – 1.0 inch (0.8 – 2.5 cm) thick, under non-motion conditions. It is not intended for use in high-acuity environments, such as ICU or operating rooms where continuous monitoring is expected.
Testing:	Nonin's Model 9591 Finger Pulse Oximeter has successfully undergone both laboratory and clinical hypoxia accuracy testing in order to ensure that it has appropriate performance, functional features to fully comply with ISO 80601-2-61:2011 and is substantially equivalent to the predicate devices.
Functional and Safety Testing:	The results of the testing demonstrate equivalency with the predicate devices and compliance to recognized standards. **Table 1** summarizes test results for the proposed devices, which met the relevant requirements of the applicable recognized standards.

Table 1

Test	Reference	Result
Electrical Safety	IEC 60601-1	Pass
Temperature and Humidity	IEC 60601-1	Pass
Atmospheric Pressure (Altitude)	IEC 60601-1	Pass
Electromagnetic Immunity and Emissions	IEC 60601-1-2	Pass
Performance	ISO 80601-2-61 IEC 60601-1 IEC 60601-1-6 IEC 60601-1-11 IEC 62304 ISO 14155	Pass
Ingress Protection	ISO 80601-2-61	Pass
Diaphoretic related ingress	Internal performance characterization	Pass
Mechanical Durability	IEC 60601-1 ISO 80601-2-61	Pass
Biocompatibility	ISO 10993-1	Pass

Clinical Testing: **Respiratory Rate Accuracy Verification Clinical (QATR10912)**
Respiratory rate accuracy testing was a comparative single-center, randomized study. The respiratory rate output of the Onyx 3 fingertip oximeter was compared to Capnography based respiratory rate. This was a minimal risk study using a non-significant risk device. A total of 30 subjects were enrolled in the study. Up to 3 subjects were enrolled per day. Subject participation lasted up to 2 hours. Demographic and anthropometric data (date of birth, gender, ethnicity, race, height, weight, skin tone and finger dimensions) were collected for all subjects. Accuracy data was calculated using both mean error and root mean square error (RMSE).

SpO_2 Accuracy Testing
SpO_2 accuracy testing was conducted at an independent research laboratory on healthy, male and female, non-smoking, light to dark-skinned subjects that were 18 years of age and older. The measured oxygen saturation value (SpO_2) of the device was compared to simultaneous arterial blood samples as assessed by co-oximetry. The accuracy of the device in comparison to the co-oximeter samples was measured over the SaO_2 range of 70-100% in motion and non-motion conditions. Accuracy data was calculated using the root-mean-squared (A_{RMS} value) for all subjects.

Summary of Substantial Equivalence:

The Model 9591 Onyx® 3 Finger Pulse Oximeter has the following similarities to its respective predicate Nonin device:

- Similar SpO_2 and Pulse Rate ranges
- Identical SpO_2 and Low Perfusion SpO_2 accuracy specifications
- Identical critical optics technology
- Perform equivalently to the similar specifications

The following lists the differences and the rationale for those differences between the proposed device and the predicate devices:

- Indications for Use: the proposed and predicate Nonin devices have identical Indications for Use and identical patient population, with the exception of the respiratory rate feature in the proposed device. The Nellcor device is a tabletop device with the additions of an alarm feature and expanded patient population, which Nonin is not seeking claims for.
- Respiratory Rate: the Nonin predicate device does not have the respiratory rate feature. The Nonin proposed device and the Nellcor predicate have similar respiratory rate ranges.
- SpO_2 accuracy with Motion: Nonin is not seeking motion claims similar to the predicate Nellcor device.
- Pulse accuracy with Motion: Nonin is not seeking motion claims similar to the predicate Nellcor device.
- Enclosure – Ingress Protection: the proposed and predicate Nonin devices are identical and offer more ingress protection than the Nellcor device.
- Battery Input: the proposed and predicate Nonin devices are identical. The Nellcor device is a tabletop-type device with a rechargeable battery (Li-Ion battery). The Nonin devices do not use rechargeable batteries.

Category	Identical/Similar/ Different (rationale)	Predicate: Model 3230 (K131021, cleared 9/11/15)	Predicate: Nellcor™ Bedside Respiratory Patient Monitoring System (K141518, cleared 3/6/15)	Proposed: Model 9591
Indications for Use				
Indications for use and Intended Use from Labeling	Different	The Model 3230 Finger Pulse oximeter is a small, lightweight portable device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO_2) and pulse rate of patients who are well or poorly perfused. It is intended for spot checking of adult and pediatric patients on digits between 0.3 – 1.0 inch (0.8 – 2.5 cm) thick.	The Nellcor™ Bedside Respiratory Patient Monitoring System is a portable pulse oximeter intended for prescription use only as a continuous non-invasive monitor of arterial oxygen saturation (SpO_2) and pulse rate of adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused. The monitoring system is intended for use in hospitals, hospital-type facilities, and during intra-hospital transport. The OxiMax SPD™ Alert (SPD) feature is intended only for facility-use care of adults to detect patterns of desaturation indicative of repetitive reductions in airflow through the upper airway and into the lungs.	The Nonin® Model 9591 Finger Pulse Oximeter is a small, lightweight, portable spot-check device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO_2) and pulse rate of patients who are well or poorly perfused. The Respiration Rate parameter provides a non-invasive measurement of respiration rate, in breaths per minute. For % SpO_2, pulse rate, and respiration rate the 9591 is intended for use in professional healthcare and home healthcare settings in adult and pediatric patients who are well or poorly perfused, with digits that are between 0.3 – 1.0 inch (0.8 – 2.5 cm) thick.
SpO_2 Range	Similar	0% to 100% SpO_2	1% to 100% SpO_2	0% to 100% SpO_2
Pulse Rate Range	Similar	18-321 BPM	20 to 250 BPM	18-321 BPM
Respiration Rate	Different	NA	4 to 40 breaths/minute	3 to 44 breaths/minute
SpO_2 Accuracy				
Adult /Pediatric SpO_2	Identical	±2 digits (± 1 A_{rms})	70 to 100% ±2 digits	±2 digits (± 1 A_{rms})
Low Perfusion SpO_2	Identical	±2 digits (± 1 A_{rms})	70 to 100% ±2 digits	±2 digits (± 1 A_{rms})
Adult /Pediatric SpO_2 with Motion	Different	NA	70 to 100% ±3 digits	NA
Pulse Rate Accuracy				
Adult and Pediatric Pulse Rate	Identical	20 to 250 BPM ±3 digits	20 to 250 BPM ±3 digits	20 to 250 BPM ±3 digits
Low Perfusion Pulse Rate	Similar	40 to 240 BPM ±3 digits	20 to 250 BPM ±3 digits	40 to 240 BPM ±3 digits
Adult/Pediatric Pulse Rate with Motion	Different	NA	48 to 127 BPM ±5 digits	NA
Device Specifications				
Measurement Wavelength	Identical	660 and 910 nanometers	660 and 900 nanometers	660 and 910 nanometers
Operating Altitude	Similar	Up to 13,123 feet	-1,000 ft. to 15,000 ft.	Up to 13,123 feet
Operating Temperature	Similar	-5° to +40°C	5° to 40°C	-5° to +40°C
Storage/Transportation Temperature	Similar	-40° to +70°C	-20° to +70°C	-40° to +70°C
Operating Humidity	Similar	10 – 95% non-condensing	15 – 95% non-condensing	10 – 95% non-condensing
Storage/Transportation Humidity	Similar	10 – 95% non-condensing	15 – 95% non-condensing	10 – 95% non-condensing
Power Requirements	Similar	3 volts DC	7.2 volts DC	3 volts DC
Battery Life (Operating)	Similar	2200 Spot Checks	6 hours	2000 Spot checks 25 hours continuous
Battery Life (Storage)	Different	1 month, with batteries installed	4 months	1 month, with batteries installed
Electrical – Type and Degree of Protection	Identical	Type BF Internally powered	Type BF Internally powered	Type BF Internally powered
Enclosure – Degree of Ingress Protection	Different	IP32	IPX1	IP32
Modes of Operation	Similar	Spot-check	Continuous	Spot-check
Battery Input	Different	Two 1.5 volt AAA-size batteries	30 VAC maximum	Two 1.5 volt AAA-size batteries
7-Segment 3-Digit Displays	Identical	Multi-pixel 3-Digit Displays (color LCD)	Not specified	Multi-pixel 3-Digit Displays (color LCD)
Pulse Strength Indicator	Identical	Color LCD	Not specified	Color LCD
Sensor Fault Indicator	Identical	Poor signal symbol followed by dashes	Not specified	Poor signal symbol followed by dashes
Low Battery Indicator	Similar	Battery Icon	Battery Icon; alarm sounds at 14%	Battery Icon
Bluetooth® Radio	Identical	Bluetooth Module 4.0	Not specified	Bluetooth Module 4.0
Materials, Direct Patient Contact				
Enclosure	Identical	Polycarbonate (PC)/Polyester	Not specified	Polycarbonate (PC)/Polyester
Finger Pads	Identical	Thermoplastic Elastomer (TPE)	Not specified	Thermoplastic Elastomer (TPE)
Battery Door	Identical	Polycarbonate (PC)	Not specified	Polycarbonate (PC)

Conclusion:

Based on the results of the above referenced testing, the same critical optics technology and risk management assessment, Nonin Medical has determined that the proposed Model 9591 Finger Pulse Oximeter is substantially equivalent to the Model 3230 finger pulse oximeter cleared by the FDA under K131021 on 9/11/2013, manufactured by Nonin Medical, Inc, without raising different questions of safety and effectiveness.